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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/787,473	02/26/2004	Milind Rajadhyaksha	ML-0493C	6991

7590 12/29/2004

Kenneth J. LuKacher
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Suite 204
3136 Winton Road South
Rochester, NY 14623

EXAMINER

PUNNOOSE, ROY M

ART UNIT	PAPER NUMBER
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2877

DATE MAILED: 12/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/787,473

Applicant(s)

RAJADHYAKSHA ET AL.

Examiner

Roy M. Punnoose

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-43 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 37-40 is/are allowed.
- 6) ☒ Claim(s) 26, 30-34 and 41 is/are rejected.
- 7) ☒ Claim(s) 27-29, 35-36, 42-43 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/9/04</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Pre-Amendment

1. Receipt of applicant's preliminary amendment received on February 26, 2004 is acknowledged. Accordingly, Claims 1-25 have been cancelled and new claims 26-43 are pending in the case.

Information Disclosure Statement

2. The information disclosure statement filed June 09, 2004 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. The documents listed under "Other Documents" have not been considered because they have not been submitted by the applicant, or are missing in the file.

Claim Objections

3. Claim 26 is objected to because of the following informalities: With regard to the recitation "receiving returned illumination" (lines 3-4), it is not clear if the returned illumination is from the tissue or some other source or object. There is no indication of any light "reflected" from the tissue, or "transmitted" through the tissue, in the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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5. Claim 30 is rejected because it recites the limitation "said tissue under tension" in line 2. There is insufficient antecedent basis for this limitation in the claim.

6. Claim 41 is rejected because it recites the limitation "said second polarization" in line 9. There is insufficient antecedent basis for this limitation in the claim.

7. Independent claims 26, 33, and 37 indicate the intention of polarization of returned illumination whereas claim 41 does not. The Examiner believes this is an unintentional omission on the part of the applicant. Therefore for examination purposes, it is assumed that polarization of returned illumination is present in claim 41.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 26 and 30-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kimura (US_5,260,569) in view of Zavislan (US_6,134,010).

10. Claims 26, 31-32 are rejected because:

A. Kimura discloses a system (see Figure 1 comprising a light source 10 (see col.5, line 36) for producing an illumination beam 11, optics 13, 16, 17 for scanning and focusing said illumination beam into sample 23 and receiving returned illumination 11'' in which the illumination beam 11 and returned illumination 11'' are cross polarized (see col.6, lines 29-50, and specifically lines 46-49) with respect to each other, said system used for scanning and providing an accurate image of said sample so that various characteristics

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of the sample can be analyzed. However, Kimura does not disclose that returned illumination when imaged represents a section of a tissue sample, the system used for scanning and providing an accurate image of said tissue sample so that various characteristics of the tissue sample can be analyzed.

- B. Zavislan discloses a system in which returned illumination when imaged represents a section of a tissue sample (see abstract, Figure 1), the system used for scanning and providing an accurate image of said tissue sample so that various characteristics of the tissue sample can be analyzed.
- C. In view of Zavislan's teachings, it would have been obvious to one of ordinary skills in the art at the time the invention was made to incorporate Zavislan's teaching of the imaging of a tissue sample into Kimura's system due to the fact that such a system would provide a more versatile system for scanning and providing accurate images of tissue samples so that various characteristics of the tissue samples can be analyzed.

11. Claim 30 is rejected for the same reasons of rejection of claim 26 above and additionally because the examiner takes official notice that "a container for holding a sample tissue" for analyzing the sample under an optical instrument is old and well known in the art.

12. Claims 33-34 are rejected for the same reasons of rejection of claim 26 above and additionally because the examiner takes official notice that various "image enhancing agents" are known in the art, such as chemical dyes, for enhancing the image of a sample under test.

Allowable Subject Matter

13. Claims 27-29 and 35-36 are objected to because it is dependent on a rejected base claims, but would be allowable if rewritten to overcome the rejection(s) to the base claims set forth in this Office action.

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14. Claim 41 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

15. Claims 42-43 are objected to because they are dependent on a rejected base claim, but would be allowable if the rejection to the base claim can be overcome, or rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

16. Claims 37 and 41 are allowable because the prior art of record, taken alone or in combination, fails to disclose or render obvious a system or method for scanning tissue or detect cancerous tissue cells comprising polarizing both the illumination light and the light returned from the tissue and controlling or adjusting the polarization of the illumination or returned beam, in combination with the rest of the limitations of the respective claims.

17. Claims 38-40 and 41-43 are allowable because they are dependent on independent claims 37 and 41 respectively, or an intermediate claim.

Conclusion

18. Several facts have been relied upon from the personal knowledge of the examiner about which the examiner took Official Notice in this office action. Applicant must seasonably challenge well known statements and statements based on personal knowledge when they are made. In re Selmi, 156 F.2d 96, 70 USPQ 197 (CCPA 1946); In re Fischer, 125 F.2d 725, 52 USPQ 473 (CCPA 1942). See also In re Boon, 439 F.2d 724, 169 USPQ 231 (CCPA 1971) (a challenge to the taking of judicial notice must contain adequate information or argument to create on its face a reasonable doubt regarding the circumstances justifying the judicial notice). If applicant does not seasonably traverse the well-known statement during examination, then the object of the well known statement is taken to be admitted prior art. In re Chevenard, 139 F.2d

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71, 60 USPQ 239 (CCPA 1943). A seasonable challenge constitutes a demand for evidence made as soon as practicable during prosecution. Thus, applicant is charged with rebutting the well-known statement in the **next reply** after the Office action in which the well known statement was made.

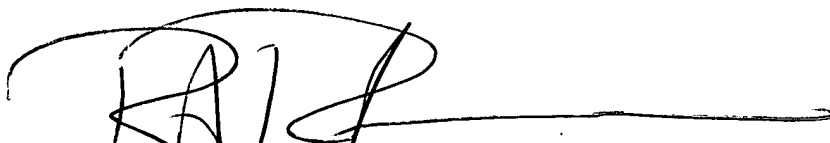
19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Roy M. Punnoose** whose telephone number is **571-272-2427**.

The examiner can normally be reached on 9:00 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Gregory J. Toatley, Jr.** can be reached on **571-272-2059**. The fax phone number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Roy M. Punnoose
Patent Examiner
Art Unit 2877
December 23, 2004


for **Gregory J. Toatley, Jr.**
Supervisory Patent Examiner

Richard A. Rosenberger
Primary Examiner